

REMARKS

A. BACKGROUND

The present Amendment is in response to the Office Action mailed August 17, 2010. Claims 1-3, 5, 6, 9, 11, 12, 15, 16, and 21-28 were pending and rejected in view of cited art. Claims 1 and 23 are amended. Claims 1-3, 5, 6, 9, 11, 12, 15, 16, and 21-28 remain pending in view of the above amendments, with claims 1 and 23 being independent.

Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. For the Examiner's convenience and reference, Applicant's remarks are presented in the order in which the corresponding issues were raised in the Office Action.

Please note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited references and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. In addition, Applicant requests that the Examiner carefully review any references discussed below to ensure that Applicant's understanding and discussion of the references, if any, are consistent with the Examiner's understanding.

B. REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

The Office Action rejected claims 1-3, 5, 6, 9, 11, 12, 15, 16, and 21-28 under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. To advance prosecution, and notwithstanding Applicant disagreeing with the Examiner regarding the scope of the specification, and in view of the amendments to independent claims 1 and 23, Applicant respectfully requests withdrawal of the rejection under Section 112.

C. PRIOR ART REJECTIONS

I. REJECTION UNDER 35 U.S.C. § 103

The Office Action rejected claims 1-4, 9, 10, 21-26, and 27 under 35 U.S.C. § 103(a) as being unpatentable over European Publication No. EP1132059 (*Johnson*) in view of U.S. Patent No. 5,295,959 (*Gurbel*), U.S. Publication No. 2003/0060832 (*Guinan*), U.S. Patent No. 6,161,029 (*Spreigl*), U.S. Patent No. 6,238,430 (*Klumb*), U.S. Patent No. 5,242,451 (*Harada*),

U.S. Patent No. 4,886,062 (*Wiktor*), U.S. Patent No. 5,308,356 (*Blackshear Jr.*), and optionally U.S. Patent No. 5,352,199 (*Tower*).

Applicants respectfully submit that the independent claims as presented for reconsideration are not anticipated nor made obvious by *Johnson* either singly or in combination with any other reference of record.¹ *Johnson* discloses a balloon catheter with balloon shoulders (Title). As described in *Johnson*, "[t]he balloon is folded into any suitable or preferable number of longitudinal pleats which are wrapped around a portion of the catheter shaft" (Para. 0031). "[A] stent is slipped onto the pleated balloon . . . [and] then gently crimped or compressed around the balloon" (Para. 0032). "[T]he resultant balloon catheter and stent assembly is then placed in a tubular mold" (Para. 0033). "The balloon is then *pressurized by applying a pressurized fluid* to the inflation port" and "the mold with accompanying balloon catheter and stent assembly . . . are held in a hot box or heated die" (Para. 0035 and 0036)(emphasis added). In another configuration, a "phantom stent" replaces the "stent" and the balloon is formed using the "phantom stent," which is subsequently removed following balloon formation.

In both of the above-described cases, the balloon is pressurized and then heated to form the shoulders and other structures of the balloon. No teaching or suggestion is made of "leaving the member wrapped around the folded balloon for a predetermined period of time to form the protrusions in the folded balloon from the uncompressed portions of the folded balloon," as recited in independent claims 1 and 23. Rather, the method of *Johnson* utilizes pressurizing the balloon from a folded state to the inflated state, i.e., from a folded balloon to an inflated balloon, and heat setting to form the protrusions. This is contrary to the method recited in independent claims 1 and 23 where the method includes "leaving the member wrapped around the *folded balloon for a predetermined period of time*" and "removing the member from the *folded balloon after the predetermined period of time and after formation of the protrusions from the uncompressed portions of the folded balloon.*" Leaving a wrapped member on a "folded balloon for a predetermined period of time *to form the protrusions in the folded balloon*" is different from pressurizing a balloon from a folded state to an inflated state to form the protrusions in the balloon as taught by *Johnson*.

¹ Any amendments to claims other than those which are expressly relied upon in overcoming the rejections on art have been made simply to insure consistency in claim language, to correct typographical or grammatical errors, or to correct other errors of a formal, non-substantive nature, but not to otherwise narrow the claims in scope for any reason.

Turning to *Gurbel*, *Guinan*, and *Blackshear*, which were cited as secondary references, *Gurbel* was cited for the proposition that it discloses "recesses are created with the use of a wrapped phantom stent during the molding step" (Office Action, p. 5). As with *Johnson*, *Gurbel* provides no teaching or suggestion of a member being left on the "*folded balloon for a predetermined period of time to form the protrusions in the folded balloon*" and then "removing the member" to allow placement of the stent. Rather, in one configuration, *Gurbel* describes wrapping the balloon with a band prior to the heat treatment in the "inflated condition" (see col. 6, ll. 32-35).

With respect to *Guinan*, it was cited for the proposition that it discloses "that one of ordinary skill would consider it functionally equivalent to form protrusions in catheter balloon by either inflating non-compressed portions of the balloon or simply using radially-compressive force to form a profile in the balloon while the balloon is in a deflated state ([0021]) and applying heat to the balloon ([0020])" (Office Action, pp. 5 and 6). Applicant respectfully disagrees. The teaching of *Guinan* taken as a whole teaches that the steps 65, 70 or shoulders "may be formed after deflation of balloon 10 by wrapping balloon 10 around shaft 50 and crimping stent 60 around intermediate body 12. . . . In this way, steps 65, 70 can be formed without pressurizing balloon 10" (Para. 0021). No mention is made of removing the crimped stent 60 from the balloon or the formation of protrusions at other locations of the balloon apart from the steps 65, 70. As such, *Guinan* alone neither teaches nor suggests a method of "creating protrusions on the folded balloon . . . leaving the member wrapped around the folded balloon . . . to form the protrusions . . . removing the member . . . and . . . positioning a stent . . . such that the protrusions previously formed in the folded balloon extend through the plurality of apertures defined by the stent" Even assuming, *arguendo*, that *Guinan* is properly combinable with *Johnson*, such combination is clearly distinguished by the claims because no mention is made of removing the crimped stent once the steps 65, 70 have been formed. Furthermore, Applicant respectfully submits that the proposed combination is inappropriate because *Guinan* teaches the use of a crimped stent, while the "phantom stent" of *Johnson* is not crimped in place because "the plastic phantom stent will not crimp in the same way that an actual metal stent does" (*Johnson* at para. 0041). Because the proposed combination would change the non-metallic stent to a metallic stent, which is contrary to the underlying reasoning behind utilizing a "phantom stent . . . that . . . costs much less than an actual metal stent", the proposed combination would

change the principle of operation of *Johnson* with the removable "phantom stent." Consequently, *Johnson* teaches away from such a combination.

Thus, *Johnson* clearly does not anticipate or make obvious applicants' claimed stent (e.g., see claims 1 and 23) which requires, *inter alia*,

- "following taking the balloon out of a mold, folding the balloon to form a folded balloon . . . after folding the balloon, wrapping a member around the balloon . . . leaving the member wrapped around the folded balloon for a predetermined period of time to form protrusions in the folded balloon from the uncompressed portions of the folded balloon . . . removing the member from the folded balloon after the predetermined period of time and after formation of the protrusions; and . . . positioning a stent" on the balloon (Claim 1 and 23, emphasis added)

Accordingly, for at least the reasons noted, independent claims 1 and 23 and the claims depending therefrom² are neither anticipated nor made obvious by *Johnson*, either singly or in combination with any other prior art of record³, and thus reconsideration and withdrawal of the rejection is respectfully requested.

D. CONCLUSION

In view of the foregoing, Applicant respectfully submits that the other rejections to the claims are now moot and do not, therefore, need to be addressed individually at this time. It will be appreciated, however, that this should not be construed as Applicant acquiescing to any of the

² Emphasis herein of the differences between the independent claims and the prior art are equally applicable to the dependent claims 2-3, 5, 6, 9, 11, 12, 15, 16, 21-22, and 24-28, but this does not mean, on the other hand, that these are necessarily the *only* differences between the claimed invention and the prior art of record. Applicants thus do not acquiesce in any asserted rejections of the dependent claims 2-3, 5, 6, 9, 11, 12, 15, 16, 21-22, and 24-28.

³ *Spreigl*, *Klumb*, *Harada*, *Wiktor*, *Blackshear*, and *Tower* were cited as additional secondary references. *Blackshear* was cited for the proposition that it discloses "that one well known method of making a balloon catheter is to introduce a tube into a mold and inflate in the tube into the shape of the balloon" (Office Action, p. 6). *Spreigl*, *Klumb*, *Harada*, and *Wiktor* were cited for that proposition that they each disclose "use of stents with a plurality of apertures between adjacently spaced loops in the stents" (Office Action, p. 3). *Harada* was also cited for the proposition that it discloses a "stent has a flat-band shape," *Spreigl* was also cited for the proposition that it discloses "a catheter with a thread-like cross-section" and *Klumb* was cited for the proposition that they disclose "a thread-like stent" (Office Action, pp. 6 and 7). *Tower* was cited as for the proposition that "it is well known in the art to first create a shaped balloon (with an inflation step) and then afterwards attach it to catheter tubing" (Office Action, pp. 6 and 7). That said, none of these references otherwise add anything in terms of reading on the claims as amended herein, particularly in reference to those claimed limitations noted above which clearly define over *Johnson*. Thus, even assuming *arguendo* that any of the references to *Spreigl*, *Klumb*, *Harada*, *Wiktor*, *Blackshear*, and *Tower* are properly combinable with *Johnson*, such combinations are clearly distinguished by the claims for the reasons already noted in reference to *Johnson*.

purported teachings or assertions made in the last action regarding the cited art or the pending application, including any official notice. Instead, Applicant reserves the right to challenge any of the purported teachings or assertions made in the last action at any appropriate time in the future, should the need arise. Furthermore, to the extent that the Examiner has relied on any Official Notice, explicitly or implicitly, Applicant specifically requests that the Examiner provide references supporting the teachings officially noticed, as well as provide the required motivation or suggestion to combine references with the other art of record.

For at least the foregoing reasons, Applicant respectfully submits that the pending claims are neither anticipated by nor made obvious by the art of record. In the event that the Examiner finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney.

Dated this 16th day of November, 2010.

Respectfully submitted,

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